Remarks

Claims 1-20 are currently pending in the application.

Restriction has been required under 35 U.S.C. § 121 to one of the following groups:

Group I, claims 1-12 and 16-20, drawn to a method, allegedly classified in class 514, subclass 34; and

Group II, claims 13-15, drawn to a composition, allegedly classified in class 424, subclass 454.

For the purpose of providing a complete response to the present Office Action, Applicant elects Group I, claims 1-12 and 16-20. Applicant respectfully traverses the restriction requirement for the reasons set out below.

Under MPEP § 803 there are two criteria that must both be met before a restriction requirement is proper: (1) The inventions must be independent or distinct as claimed, and (2) there must be a serious burden on the examiner if restriction is not required. The initial burden is on the examiner to provide reasons with respect to both of these requirements. MPEP § 803.

The Office Action alleged that Group II and Group I are related as a product and a process of use. MPEP § 806.05(h) states that a product a process of using the product can be shown to be distinct inventions if either of both of the following can be shown: (A) the process of using the product *as claimed* can be

practiced with another materially different product; or (B) the product as claimed can be used in a materially different process. The Office Action stated, "[i]n the instant case the process of using the product as claimed can be practiced with another materially different product such as a hydrophobic solvent." The product as claimed is a composition that includes a micellar drug carrier and a hydrophobic drug. The micellar drug carrier contains at least the following elements: (1) a hydrophobic core, in which the hydrophobic drug is contained, and (2) a mixture of (a) a PEGylated diacylphospholipid, and (b) an AB-diblock copolymer, an ABA-triblock copolymer, or a mixture of an AB-diblock copolymer and an ABA-triblock copolymer. How a hydrophobic solvent could be substituted for this composition, as alleged in the Office Action, for administration of a drug to a patient and applying ultrasound such that the hydrophobic drug is released from the hydrophobic solvent to a selected site in the patient is incomprehensible. The Office Action has simply not given a plausible explanation of how the (A) part of the test can be met. The Office Action did not address the (B) part of the test, i.e., whether the product *as claimed* can be used in a materially different process. Therefore, the Office Action failed to make a showing of distinctness between the process of using and the product. Hence, "restriction cannot

be required." MPEP § 806.05(I). Accordingly, withdrawal of the restriction requirement is respectfully requested.

Applicants further respectfully submit that there would be no serious burden on the Examiner to examine the present application in its entirety, regardless of whether or not a *prima facie* case of serious burden has been shown. For this reason, as well, withdrawal of the restriction requirement is respectfully requested.

The Office Action further required, under 35 U.S.C. § 121, election of a single disclosed species. Applicants respectfully traverse this requirement, as well. To provide a complete reply to this requirement, Applicants respectfully elect claims wherein the micellar drug carrier comprises poly(ethylene oxide)-poly(propylene oxide)-poly(ethylene oxide) triblock copolymer. Claims readable on this species are claims 1, 3-5, 7-12, and 16-20.

In conclusion, Applicant respectfully request that the restriction requirement be withdrawn and the application be examined in its entirety.

DATED this 15th day of November, 2007.

Respectfully submitted,

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